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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KRAMER, NICOLE R	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 05/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/735,519	KIM ET AL.	
	Examiner	Art Unit	
	Nicole R. Kramer	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/21/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Presently, there are two claims numbered 44. Appropriate correction is required.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 24, 28, 38, 41, and 56 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 11 of copending Application No. 10/734,599. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims require delivering a pacing pulse using one electrode configuration, sensing a cardiac signal after delivery of the pacing pulse using a different electrode configuration, establishing or defining a plurality of classification windows, and classifying the cardiac response based on a detected characteristic of the cardiac signal.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 24-34, 38, 41, and 56 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-94 of copending Application No. 70/733,869. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims require delivering a pacing pulse, sensing a cardiac signal after delivery of the pacing pulse, establishing or defining a plurality of classification windows, and classifying the cardiac response based on a detected characteristic of the cardiac signal. The claims of the '869 application do not require that the sensing a cardiac signal use a second or different electrode configuration than the configuration used for delivering a pacing pulse. It would have been obvious to modify the method/apparatus claimed in the '869 patent such that sensing a cardiac signal uses a second or different electrode

configuration than the configuration used for delivering a pacing pulse in order to verify whether a pacing pulse delivered in one heart chamber is captured in another heart chamber.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 3-4, 6, 8-9, 11-12, 15, 17-30, 32, 34-39, 41-42, 45-47, 52, 55-57, 79, and 61-62 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,456,881 ("Bornzin et al.").

Bornzin et al. discloses a method (method 300 illustrated in Fig. 3) for determining a cardiac response to a pacing pulse, which is implemented whenever microcontroller 60 performs capture verification in either or both the right and left ventricles (see col. 7, lines 17-40). A ventricular stimulation pacing pulse is delivered to the heart at step 305 (see col. 7, lines 40-45) using a first electrode combination (the ventricular stimulation pulse is necessarily delivered using either coronary sinus lead 24 or right ventricular lead 30; see col. 5, line 58 - col. 6, line 28). After the pacing pulse is

delivered, the atrial EGM is sensed (see col. 7, lines 45-54) using a second electrode combination (the atrial signal is sensed using right the tip electrode 22 of atrial lead 20 and the pacemaker housing, or using ring electrode 27 of coronary sinus lead 24 and the pacemaker housing; see col. 8, lines 9-20); and classifying the cardiac response to the pacing pulse as one of a captured response, a non-captured response, and a fusion beat using the sensed cardiac signal (at decision steps 332, 335, and 325 of Fig. 3, fusion, loss of capture, or capture is confirmed by examining the atrial sensed signal sensed at step 330; see col. 8, line 21 - col. 9, line 30).

With respect to claims 3, 4, 6, 8, 22, and 36, Bornzin et al. discloses that classifying the cardiac response comprises comparing a detected signal characteristic to a reference (the atrial sensed signal is examined to determine if a far-field R-wave signal is detected; see col. 8, line 45 - col. 9, line 5. Bornzin et al. incorporates by reference patent application 09/946,614, entitled "System and Method for Ventricular Capture using Far Field Evoked Response", filed Dec. 14, 1999, which Examiner believes was intended to recite U.S. Patent No. 6,345,201, entitled "System and Method for Ventricular Capture using Far Field Evoked Response", filed Dec. 14, 1999. The '201 patent describes that the far-field signal sensed by the atrial channel is sampled to determine its amplitude; see col. 8, lines 39-41. The FFR sample is compared to a predetermined far-field signal recognition template to verify whether the FFR sample morphology corresponds to a far-field R-wave that is expected to follow a captured ventricular stimulation pulse; see col. 5, lines 30-42 and col. 8, lines 41-50). The cardiac response is classified based on the comparison (if no FFR is detected, loss of

capture is confirmed as described at col. 9, lines 8-9. If FFR is detected, then fusion is confirmed as described at col. 9, lines 23-24).

With respect to claims 9, 23, 37, 42, and 55, the pacing pulse is delivered using a near field vector (the ventricular stimulation pulse is necessarily delivered using either coronary sinus lead 24 or right ventricular lead 30; see col. 5, line 58 - col. 6, line 28), and the atrial cardiac signal is sensed using a far-field vector (the atrial signal is sensed using right the tip electrode 22 of atrial lead 20 and the pacemaker housing, or using ring electrode 27 of coronary sinus lead 24 and the pacemaker housing; see col. 8, lines 9-20).

With respect to claims 11-12 and 47, Bornzin et al. further teaches that as part of classifying the cardiac responses, the ventricular EGM is sampled from the ventricular chamber in which stimulation is applied, which could be the left ventricle, the right ventricle, or both the left and right ventricles (see col. 7, lines 45-55). The ventricular signal may be sensed using various electrode configurations, such as between the tip electrode and the can, the ring electrode and the can, the tip electrode and the ring electrode, the coronary sinus electrode 27 and the tip electrode, etc... (see col. 7, line 55 - col. 8, line 8). The ventricular EGM is used to determine if the evoked response resulted in capture (see col. 8, lines 21-42).

With respect to claims 45-46, Bornzin et al. discloses that the ventricular stimulation may be applied within the left ventricle, the right ventricle, or both (see col. 7, lines 45-55). Further, Bornzin et al. discloses that the either the right or left atrial EGM signal may be used to classify the cardiac response (see col. 8, lines 9-20).

With respect to claims 20 and 21, Bornzin et al. explicitly discloses classifying the cardiac response to the pacing pulse as one of a captured response, a non-captured response, and a fusion beat using the sensed cardiac signal (at decision steps 332, 335, and 325 of Fig. 3, fusion, loss of capture, or capture is confirmed by examining the atrial sensed signal sensed at step 330; see col. 8, line 21 - col. 9, line 30). Examiner considers classification of a captured response in Bornzin et al. to necessarily include classification of a near non-captured response, because both responses result in a captured stimulation pulse. Further, Examiner considers classification of non-captured response in Bornzin et al. to necessarily include a non-captured response added to an intrinsic beat, because both responses result in a non-captured, stimulation pulse.

With respect to claims 24, 28-30, 32, 34, 38, 41, and 56, Bornzin et al. discloses that immediately after the Vpulse, the atrial and ventricular EGMS are sampled and stored for a predefined time such as 50-100 msec (see col. 7, lines 46-54). Microcontroller 60 first determines if an evoked response is detected from the sampled ventricular sample in order to see if capture is confirmed (see col. 8, lines 21-42). If capture is not confirmed, microcontroller 60 examples the atrial sensed signal to determine is a FFR signal was detected to confirm either fusion or loss of capture (see col. 8, line 43 - col. 9, line 30). Examiner considers these decision steps (i.e., sampling of the cardiac signals, examination of the ventricular signal, examination of the atrial signal) to be "a plurality of classification windows relative to and subsequent to the pacing pulse." A characteristic of the cardiac signal is detected within a particular classification window (the atrial sensed signal is examined to determine if a far-field R-

wave signal is detected; see col. 8, line 45 - col. 9, line 5. Bornzin et al. incorporates by reference patent application 09/946,614, entitled "System and Method for Ventricular Capture using Far Field Evoked Response", filed Dec. 14, 1999, which Examiner believes was intended to recite U.S. Patent No. 6,345,201, entitled "System and Method for Ventricular Capture using Far Field Evoked Response", filed Dec. 14, 1999. The '201 patent describes that the far-field signal sensed by the atrial channel is sampled to determine its amplitude; see col. 8, lines 39-41. The FFR sample is compared to a predetermined far-field signal recognition template to verify whether the FFR sample morphology corresponds to a far-field R-wave that is expected to follow a captured ventricular stimulation pulse; see col. 5, lines 30-42 and col. 8, lines 41-50); and the cardiac response to the pacing pulse is classified based on the detected characteristic and the particular classification window (if no FFR is detected, loss of capture is confirmed as described at col. 9, lines 8-9. If FFR is detected, then fusion is confirmed as described at col. 9, lines 23-24).

With respect to claims 57-62, Examiner notes that Applicant has invoked 112, sixth paragraph. Examiner considers the "means for" performing the recited claim elements to be equivalent to the means disclosed in Bornzin et al. (such as the leads, electrodes, and sensing circuitry, and pulse generators for pacing and sensing cardiac signals as described at col. 5, line 50 - col. 6, line 50; and a microcontroller 60 for classifying the cardiac responses as described at col. 7, lines 16-40).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 2, 16, 40, 53, 58, and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,456,881 ("Bornzin et al."), as applied above, in view of U.S. Patent No. 5,522,860 ("Molin et al.").

Bornzin et al. teaches that the microcontroller 60 includes timing circuitry for keeping track of noise detection windows (see col. 10, lines 57-64), but fails to explicitly disclose that if noise is detected on the cardiac signal, the classification of the cardiac response is canceled. Molin et al. teaches that it is well known in the art to determine the presence of noise, and suspend a function of the device if there is too much noise (see Abstract). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the method of identifying fusion as disclosed in Bornzin et al. such that if noise is detected on the cardiac signal, the classification of the cardiac response is canceled/suspended as taught by Molin et al. in order to avoid classifying cardiac signals which contain too much noise (which would necessarily lead to an improper classification and therefore may lead to an improper response/therapy being delivered).

9. Claims 5, 7, 31, and 33, are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,456,881 ("Bornzin et al.") in view of U.S. Patent No. 6,738,669 ("Sloman et al.").

As described above, Bornzin et al. discloses that the atrial sensed signal is examined to determine if a far-field R-wave signal is detected; see col. 8, line 45 - col. 9, line 5. Bornzin et al. incorporates by reference patent application 09/946,614, entitled "System and Method for Ventricular Capture using Far Field Evoked Response", filed Dec. 14, 1999, which Examiner believes was intended to recite U.S. Patent No. 6,345,201, entitled "System and Method for Ventricular Capture using Far Field Evoked Response", filed Dec. 14, 1999. The '201 patent describes that the far-field signal sensed by the atrial channel is sampled to determine its amplitude; see col. 8, lines 39-41. The FFR sample is compared to a predetermined far-field signal recognition template to verify whether the FFR sample morphology corresponds to a far-field R-wave that is expected to follow a captured ventricular stimulation pulse; see col. 5, lines 30-42 and col. 8, lines 41-50. Bornzin et al. fails to disclose that detecting the characteristic comprises detecting a slope or pulse width of the cardiac signal and comparing the detected characteristic to a reference comprises comparing the detected slope/pulse width to a slope/pulse width reference. Sloman et al. teaches that there are many standard methods known in the art for comparing various features of an evoked R-wave to an expected value to determine if the sampled far-field signal is indeed a far-field R-wave, such as peak amplitude, the integral, the slope, the morphology, or another characteristic feature (see col. 12, lines 50-60). It would have been obvious to

one having ordinary skill in the art at the time of applicant's invention to modify the method of identifying fusion as disclosed in Bornzin et al. such that slope and/or pulse width is utilized for determining if the sampled far-field signal is indeed a far-field R-wave as taught by Sloman et al. in order to effectively identify a far-field R-wave by standard, known methods in the art.

Further, Examiner notes that it would have been an obvious matter of design choice to utilize any characteristic feature of the evoked R-wave, including the slope or pulse width, for determining if the sampled far-field signal is indeed a far-field R-wave, since applicant has not disclosed that utilizing the slope or pulse width solves any stated problem or is for any particular purpose, and it appears that the claimed invention would perform equally well with utilizing the amplitude and morphology of the evoked R-wave as disclosed in Bornzin et al.

10. Claims 10, 43, 44 (both claims 44), and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,456,881 ("Bornzin et al.").

As discussed above, Bornzin et al. discloses that a ventricular stimulation pacing pulse is delivered to the heart at step 305 (see col. 7, lines 40-45) using a first electrode combination (the ventricular stimulation pulse is necessarily delivered using either coronary sinus lead 24 or right ventricular lead 30; see col. 5, line 58 - col. 6, line 28). Examiner considers the structure utilized for delivering the ventricular pulse to be a "rate channel vector" because such ventricular stimulation pulses necessarily control the delivered rate. After the pacing pulse is delivered, the atrial EGM is sensed (see col. 7,

lines 45-54) using a second electrode combination (the atrial signal is sensed using right the tip electrode 22 of atrial lead 20 and the pacemaker housing, or using ring electrode 27 of coronary sinus lead 24 and the pacemaker housing; see col. 8, lines 9-20). Since Bornzin et al. does not explicitly disclose that atrial coil electrode 28, which is used for shocking therapy (see col. 6, lines 3-14), may be used for sensing the atrial signal, Bornzin et al. fails to disclose that a shock channel vector may be utilized for sensing the cardiac signal. It would have been an obvious matter of design choice to utilize coil electrode 28 for sensing the far-field atrial signal, since applicant has not disclosed that utilizing a shock channel vector solves any stated problem or is for any particular purpose, and it appears that the claimed invention would perform equally well with utilizing any electrode which detects the far-field atrial signal.

With respect to claims 44, Bornzin et al. further teaches that as part of classifying the cardiac responses, the ventricular EGM is sampled from the ventricular chamber in which stimulation is applied, which could be the left ventricle, the right ventricle, or both the left and right ventricles (see col. 7, lines 45-55). The ventricular signal may be sensed using various electrode configurations, such as between the tip electrode and the can, the ring electrode and the can, the tip electrode and the ring electrode, the coronary sinus electrode 27 and the tip electrode, etc... (see col. 7, line 55 - col. 8, line 8). The ventricular EGM is used to determine if the evoked response resulted in capture (see col. 8, lines 21-42). Bornzin et al. does not explicitly disclose that the coil electrode may be used for sensing the ventricular signal. It would have been an obvious matter of design choice to utilize the coil electrode for sensing the ventricular signal, since

applicant has not disclosed that utilizing the coil electrode solves any stated problem or is for any particular purpose, and it appears that the claimed invention would perform equally well with utilizing any electrode which detects the ventricular signal.

11. Claims 13-14 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,456,881 ("Bornzin et al.") in view of U.S. Patent No. 6,434,428 ("Sloman et al").

Bornzin et al. discloses a method for ventricular capture verification, in which stimulation pulses are applied to one or both of the ventricles, and the atrial EGM signal is used for distinguishing loss of capture from fusion (see col. 7, line 16 - col. 9, line 30). Bornzin et al. fails to disclose that the methodology for verifying capture may be used in an atrial capture verification test, in which the pacing pulse is delivered to an atrium. Sloman et al. discloses an atrial verification test in which a stimulation pulse is delivered to the atrium, and the atrial lead is used for sensing a far-field signal which distinguishing capture from non-capture (see col. 10, line 54 - col. 12, line 11). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the method of identifying fusion as disclosed in Bornzin et al. such that the stimulation pulse is delivered to an atrium such that the sensed cardiac signal can be used to verify atrial capture as well as ventricular capture.

12. Claims 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,456,881 ("Bornzin et al.") in view of U.S. Patent No. 4,878,497 ("Callaghan et al.").

Bornzin et al. fails to disclose that the pulse delivery circuit further comprises a coupling capacitor through which the pacing pulse is delivered. Callaghan et al. teaches a pacemaker for distinguishing between a fusion beat and loss of capture, in which the pulse delivery circuit further comprises a coupling capacitor through which the pacing pulse is delivered (see col. 5, lines 5-15, which describe that output coupling capacitor 60 is utilized for delivering the electrical charge in order to quickly diminish the post-stimulus polarization of the electrode). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the system for identifying fusion as disclosed in Bornzin et al. to include a coupling capacitor as taught by Callaghan et al. in order to quickly diminish the post-stimulus polarization of the electrode.

With respect to claim 51, it would have been obvious to one having ordinary skill in the art at the time of applicant's invention for the coupling capacitor to have a range of about 2 microfarads to about 22 microfarads, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *See, for example, In re Aller,* 105 USPQ 233.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

U.S. Patent No. 5,324,310 teaches a method for verifying capture in which pacing is performed in a unipolar configuration from the respective tip electrodes, and sensing is performed between the ring electrodes of the leads.

U.S. Patent Application Publication 2002/0183798 teaches a method and system for atrial capture detection based on far-field R-wave sensing.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole R. Kramer whose telephone number is 571-272-8792. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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5/2/06

George Manuel